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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Bernard Savord

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02/18/2009

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EXAMINER

CHENG, JACQUELINE

ART UNIT

PAPER NUMBER

3768

MAIL DATE

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02/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,212	Applicant(s) SAVORD ET AL.	
	Examiner JACQUELINE CHENG	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed November 19, 2008 have been fully considered but they are not persuasive. The examiner respectfully disagrees with the applicant's arguments. The applicant argues that Hunter (US 2004/0097806 A1) describes a system that is designed to place an icon on a 2D ultrasound image and where the image is a pre-acquired image, however, this is just one example of how Hunter can be used. Hunter discloses that either pre-operative or real-time images can be used and also discloses that instead of using 2D ultrasonic images that other imaging modalities can be used such as 3D ultrasound (which would inherently require a two dimensional array transducer). Hunter also discloses in particular that the images be obtained and displayed in two or three dimensions, and that one of the ways to display the three dimensional image is to convert, such as rendering, to three-dimensional volumetric images (paragraph 0039). Hunter also discloses that real time MR allows catheter navigation while visualizing the infarcted region of the heart, and that the navigation system provides catheter registration to the images, whether fluoroscopic or volume rendered (paragraph 0062). Therefore Hunter teaches the catheter icon displayed in a 3D image.

2. The applicant further argues that Hunter cannot anticipate the claims because "Hunter does not even use the word "rendering." ". The examiner respectfully disagrees and would like to point out to the applicant that Hunter uses rendering a few times in the specification, for example in paragraph 0039 "In more advanced forms, four-dimensional surface *rendering* of the heart..." and in paragraph 0062 "also catheter registration to the images, whether fluoroscopic of volume-

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rendered using...", and again in paragraph 0072 "the navigation system 10 utilizes a three-dimensional volume *rendered*....Once the catheter 52 is in range, it is displayed on the display relative to the *rendered* heart model."

3. For these reasons the examiner believes that Hunter still stands over the claims as previously written and over the claim amendments and the rejections as dated on August 20, 2008 still stands and is repeated below.

4. The examiner approves the entry of the abstract filed November 19, 2008.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1, 3, 4, and 6-8** are rejected under 35 U.S.C. 102(e) as being anticipated by Hunter (US 2004/0097806 A1). Hunter discloses a method and apparatus navigation system for operation of an invasive medical device. The system of Hunter comprises an imaging device such as an ultrasonic imaging device, to acquire pre-operative or real-time images of a patient. The images can be 3D volumetric rendered images which are patient registered by converting the images to a frame of reference of the system by using fiducial arrays or landmarks. The position data of the invasive medical device such as a catheter is also registered to the same frame of reference (a common reference frame). The position of the device and the ultrasonic image data

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are then combined by superimposing an image of an icon onto the ultrasonic images (paragraph 0034, 0039, 0045, 0049, 0052, 0058)

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. **Claims 2 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter and further in view of Holupka (US 6,256,529 B1). Hunter discloses most of what is claimed as discussed above except for disclosing acquiring transducer position information. Hunter disclosed that any well known imaging device such as an ultrasound device can be used, however did not explicitly disclose any information about what type of ultrasonic device as the disclosure was mainly directed at using a fluoroscopic C-arm as the imaging device. It would

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therefore be obvious to use any well known ultrasonic device in Hunter such as disclosed by Holupka. Holupka discloses an ultrasonic imaging device for placement of an invasive medical device wherein the ultrasonic imaging device comprises a digital encoder for providing information regarding the position of the ultrasonic image planes (col. 5 line 19-25). To know the image plane that is being taken is to know how the transducers are positioned as the transducers must be positioned in a certain manner to be able to image a particular plane. It would be obvious to combine the ultrasonic system of Holupka because the fluroscopic C-arm device of Hunter comprises knowing at what angle and what view of the patient is taken (paragraph 0034, 0036) so if the imaging system used was an ultrasonic device it would be desirable to also know the angle and image plane of the ultrasonic imager.

10. **Claims 9-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanelli (US 6,515,657 B1) further in view of Hunter. Zanelli discloses an ultrasound imaging system that superimposes (combines) images of a catheter on ultrasonic images of the tissue area of interest. The image data of the catheter or the image data o the tissue images can be either 3D or 4D ultrasound images (video data). Zanelli does not explicitly disclose the process of scaling and orienting the 3D image data to a certain frame of reference, however Zanelli does disclose that the image data can be collected in different coordinate systems and then converted to the preferred format using transformation techniques well known in the art. It would therefor be obvious to use transformation techniques of orienting the frames of reference of the catheter system and the tissue image such as disclosed by Hunter above.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3768

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768